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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,369	11/13/2006	Barbara Mohar	33577-US-PCT	9492
72554	7590	01/11/2008	EXAMINER	
SANDOZ INC			DAVIS, BRIAN J	
506 CARNEFIE CENTER				
PRINCETON, NJ 08540				
			ART UNIT	PAPER NUMBER
			1621	
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			01/11/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/584,369	MOHAR, BARBARA	
	Examiner	Art Unit	
	Brian J. Davis	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-39 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 20-28 and 39 is/are allowed.
- 6) ☒ Claim(s) 29-38 is/are rejected.
- 7) ☒ Claim(s) 33 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 June 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>6/23/06</u> | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Drawings

The drawings are objected to because, in Scheme 2, the third structure appears to be incorrect. That is, it appears inconsistent with the teachings of the specification and claims that the carboxylic acid moiety is transformed into an acid chloride. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The disclosure is objected to because of the following informalities: the parentage (specifically the 371 status) of the application should appear immediately after the title of the specification, or on an application data sheet (MPEP 1893.03(c)). Appropriate correction is required.

Claim Objections

Claim 33 is objected to because of the following informalities: the extraneous word "any" should be deleted from the text. Appropriate correction is required.

Applicant's assistance is respectfully requested in correcting any other minor grammatical and/or spelling errors which may be present in the claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 29 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the steps involved in "converting the deprotected group to form tamsulosin or tamsulosin hydrochloride" (step f).

Claims 30-37 are also rejected under 35 USC 112, second paragraph, as claims which depend from indefinite claims are also indefinite. *Ex parte Cordova*, 10 USPQ 2d 1949, 1952 (PTO Bd. App. 1989).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over *Chemical & Pharmaceutical Bulletin* (1992), 40(6), p. 1443-1451 (CAPLUS abstract).

Applicant claims a compound.

Chemical & Pharmaceutical Bulletin (1992), 40(6), p. 1443-1451 teaches an adjacent homolog (a difference of one carbon atom in an alkyl chain) of that compound: RN=125960-65-8.

Adjacent homologs are considered to be obvious absent unexpected results. "Presumption of unpatentability arises against [a] claim directed to [a] composition of matter the adjacent homologue of which is old in [the] art; burden is on applicant to rebut presumption by showing that [the] claimed compound possess unobvious or

unexpected beneficial properties not actually possessed by [the] prior art homologue; it is immaterial that [the] prior art homologue may not be recognized or known to be useful for [the] same purpose or to possess [the] same properties as [the] claimed compound...". This is so because: "[C]haracteristics normally possessed by members of homologous series are principally the same, and vary but gradually from member to member; chemists knowing properties of one member [of the] series would in general know what to expect of adjacent members." *In re Henze*, 85 USPQ 261, 263 (CCPA 1950). Members of a homologous series must possess unexpected properties not possessed by the homologous compounds disclosed in the prior art. *In re Hass*, 141 F.2d 127, 60 USPQ 548 (CCPA 1980). One of ordinary skill in the art would have been motivated to make the instant compound in a further search for novel α -blockers of formula (I) of the cited prior art.

Allowable Subject Matter

Claims 20-28 and 39 are allowed. The following is a statement of reasons for the indication of allowable subject matter:


The closest prior art appears to be US 3,860,647, which teaches a related synthesis (column 1, Scheme 1). The reference neither teaches nor suggests the instant route, nor its stereoselective synthesis.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Davis whose telephone number is 571-272-0638. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne (Bonnie) Eyler can be reached at 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


**BRIAN DAVIS
PRIMARY EXAMINER**

Brian J. Davis
January 6, 2008